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NOTICE OF ALLOWANCE AND FEE(S) DUE

21874 7590 0625/2009 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON. MA 02205 EXAMINER
FISHER, ABIGAIL L
ART UNIT PAPER NUMBER

1616 DATE MAILED: 06/25/2009

 APPLICATION NO.
 FILING DATE
 FIRST NAMED INVENTOR
 ATTORNEY DOCKET NO.
 CONFIRMATION NO.

 10/030,825
 01/11/2002
 Yasunori Takada
 56769 (71526)
 2372

TITLE OF INVENTION: PERCUTANEOUSLY ABSORBABLE PREPARATIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$0	\$0	\$1510	09/25/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FFE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

appropriate. All further indicated unless correcte maintenance fee notifical	correspondence includir ed below or directed oth	or transmitting the 1880 ig the Patent, advance of nerwise in Block 1, by (a	rders and notification of r a) specifying a new corres	naintenance fees will pondence address; a	I be mailed to the current and/or (b) indicating a sep	correspondence address as arate "FEE ADDRESS" for
CURRENT CORRESPOND	ENCE ADDRESS (Note: Use Bi	ock 1 for any change of address)	Note Feel paps have	e: A certificate of m s) Transmittal. This ers. Each additional p its own certificate o	ailing can only be used for certificate cannot be used baper, such as an assignmant for mailing or transmission.	or domestic mailings of the for any other accompanying ent or formal drawing, must
EDWARDS A P.O. BOX 55874 BOSTON, MA	4	^{/2009} R & DODGE LLP		Contil	Sente of Mailing or Trans	
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						(Signature)
						(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	1	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,825 TITLE OF INVENTION	01/11/2002 : PERCUTANEOUSLY	ABSORBABLE PREPA	Yasunori Takada RATIONS		56769 (71526)	2372
APPLN, TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE I	FEE TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$0	\$0	\$1510	09/25/2009
EXAM	INER	ART UNIT	CLASS-SUBCLASS			
FISHER, A	BIGAIL L	1616	424-078200	•		
"Fee Address" ind. PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A	ondence address (or Cha 3/122) attached. ication (or "Fee Address 12 or more recent) attach ND RESIDENCE DATZ less an assignee is ident h in 37 CFR 3.11. Comp	nge of Correspondence Indication form ed. Use of a Customer A TO BE PRINTED ON	2. For printing on the p (1) the names of up to or agents OR, alternativ (2) the name of a singl registered attorney or a 2 registered patent atto listed, no name will be THE PATENT (print or tyr data will appear on the p T a substitute for filing an (B) RESIDENCE: (CITY	3 registered patent avely, e firm (having as a nagent) and the names meys or agents. If no printed. te) atent. If an assignee assignment.	nember a 2 of up to name is 3	document has been filed for
Please check the appropri	iate assignee category or	categories (will not be pr	rinted on the patent):	Individual Corp	poration or other private gr	oup entity Government
4a. The following fee(s): Issue Fee Publication Fee (N	o small entity discount p		b. Payment of Fee(s): (Plea A check is enclosed. Payment by credit car The Director is hereby overpayment, to Depo	d. Form PTO-2038 i	s attached.	shown above) eficiency, or credit any un extra copy of this form).
	s SMALL ENTITY state	is. See 37 CFR 1.27.			ENTITY status. Sec 37 C	
NOTE: The Issue Fee and interest as shown by the i	d Publication Fee (if req records of the United Sta	uired) will not be accepte tes Patent and Trademark	d from anyone other than t Office.	he applicant; a registe	ered attorney or agent; or t	he assignee or other party in
Authorized Signature				Date		
Typed or printed name				Registration No.		
This collection of inform an application. Confident submitting the complete this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223	ation is required by 37 C tiality is governed by 35 d application form to the ons for reducing this but firginia 22313-1450. DC 13-1450.	FR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the ONOT SEND FEES OR	on is required to obtain or r 1.14. This collection is est r depending upon the indiv e Chief Information Office COMPLETED FORMS TO	etain a benefit by the imated to take 12 mi idual case. Any com r, U.S. Patent and Ti D THIS ADDRESS.	public which is to file (an nutes to complete, includi ments on the amount of ti rademark Office, U.S. Dep SEND TO: Commissioner	d by the USPTO to process) ng gathering, preparing, and me you require to complete sartment of Commerce, P.O. for Patents, P.O. Box 1450,

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EDWARDS ANGELL PALMER & DODGE LLP			FISHER, A	ABIGAIL L
P.O. BOX 55874			ART UNIT	PAPER NUMBER
BOSTON, MA 02205			1616	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 510 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 510 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/030 825 TAKADA ET AL. Notice of Allowability Examiner Art Unit ARIGAII FISHER 1616 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to after final amendment maile don 6/10/09. The allowed claim(s) is/are 13,14,16 and 17. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) X All b) ☐ Some* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the

attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

 Notice of Reference 	

- Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date
- 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- 6. Interview Summary (PTO-413), Paper No./Mail Date
- 7. T Examiner's Amendment/Comment
- 8. X Examiner's Statement of Reasons for Allowance
- 9. ☐ Other .

Application/Control Number: 10/030,825

Art Unit: 1616

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The instant claims are found allowable in light of the showing that a <u>non-aqueous</u> patch comprising sodium diclofenac and ammonium chloride improves the percutaneous absorbability of sodium diclofenac in comparison to a non-aqueous patch not comprising the ammonium chloride. The prior art does not recognize or teach the utilizing of ammonium chloride in combination with pharmaceutically active agents such as sodium diclofenac results in improved percutaneous absorbability.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher Examiner Art Unit 1616

ΑF

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616